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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte OLEG LLIICH EPHSTEIN

Appeal 2010-010242
Application 09/117,838
Technology Center 1600

Before ERIC GRIMES, MELANIE L. McCOLLUM, and STEPHEN WALSH, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a bipathic medication and a method for making it. The Examiner has rejected the claims as anticipated or obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 17, 19-21, 23, 25-27, 29-34, and 38-48 are pending and on appeal (App. Br.[1] 2). We will focus on claims 17 and 23, the only independent claims on appeal, which read as follows:

17. A method of making a bipathic medication, comprising the steps of:
providing an active medicinal substance in a therapeutic dose;
providing a homeopathic dilution of said active medicinal substance; and
admixing or incorporating said therapeutic dose and said homeopathic dilution with one another thus producing said bipathic medication.

23. A bipathic medication comprising a pharmaceutically active combination of
i) a therapeutic dose of an active medicinal substance; and
ii) a homeophatic [sic] dilution of said active medicinal substance; said active medicinal substance and said homeophatic [sic] dilution being admixed or incorporated with one another;
wherein said pharmaceutically-active combination possesses enhanced therapeutic properties in comparison with said active medicinal substance alone, said enhanced therapeutic properties being enhanced therapeutic effectiveness or reduced side effects.

Claims 17, 19-21, 23, 25-27, and 45-48 stand rejected under 35 U.S.C. § 102(b) as anticipated by or under 35 U.S.C. § 103(a) as obvious over Jonsson et al. (US 4,292,324, Sep. 29, 1981) (Ans. 3).

Claims 29 and 38 stand rejected under 35 U.S.C. § 102(b) as anticipated by or under 35 U.S.C. § 103(a) as obvious over Cohen et al. (US 3,901,967, Aug. 26, 1975) (Ans. 4).

[1] Amended Brief on Appeal dated May 8, 2009.

Claims 30 and 39 stand rejected under 35 U.S.C. § 102(b) as anticipated by or under 35 U.S.C. § 103(a) as obvious over Sirany (US 4,987,127, Jan. 22, 1991) (Ans. 4).

Claims 31, 40, and 41 stand rejected under 35 U.S.C. § 102(b) as anticipated by or under 35 U.S.C. § 103(a) as obvious over Nobile (US 3,134,718, May 26, 1964) (Ans. 4).

Claims 32 and 42 stand rejected under 35 U.S.C. § 102(b) as anticipated by or under 35 U.S.C. § 103(a) as obvious over Massey et al. (US 4,839,341, Jun. 13, 1989) (Ans. 5).

Claims 33 and 43 stand rejected under 35 U.S.C. § 102(b) as anticipated by or under 35 U.S.C. § 103(a) as obvious over Jonsson (Ans. 5).

Claims 43[2] and 44 stand rejected under 35 U.S.C. § 102(b) as anticipated by or under 35 U.S.C. § 103(a) as obvious over Bergel et al. (US 3,032,584, May 1, 1962) (Ans. 5).

In rejecting claims 17 and 23, the Examiner relies on Jonsson for disclosing "a method of making a pharmaceutical composition by combining one or more active substances and a method of treatment with said composition" (Ans. 3-4). The Examiner finds:

> Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the same chemical structure and combining said substances into a single composition would inherently result in the prior art's composition or a composition in which therapeutic dose is so similar to the prior art's dose as to be statistically insignificant.

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[2] Upon review of the claims, we note that the Examiner may have intended to reject claim 34 rather than claim 43 on this basis.

(*Id.* at 4.) The Examiner also finds that "admixing the same active substance in different dosages in order to prepare a composition comprising a known pharmaceutical at a therapeutic dosage would have been prima facie obvious" (*id.* at 8).

Jonsson discloses a "pharmaceutical composition containing zinc in the form of one or more water soluble zinc salts and a complex-former" and "water solutions thereof" (Jonsson, Abstract). We agree with Appellant that the Examiner has not adequately explained how Jonsson teaches or suggests the method steps of claim 17. We therefore reverse the rejections of claim 17 and of claims 19-21, which depend from claim 17.

With regard to product claim 23, we understand the Examiner's position to be that the claimed "combination would inherently result in a composition comprising said active compound in a therapeutic dose" (Ans. 6). However, Appellant has provided a Declaration purporting to demonstrate "the modification effect of the ultra low doses (ULD) of a biologically active compound on the same compound when they are administered together (combined administration)" (Dec. ¶ 5). The Examiner has not adequately explained why this evidence fails to demonstrate that the claimed composition, which requires that the "combination possesses enhanced therapeutic properties in comparison with [the] active medicinal substance alone," is different from the compositions disclosed in Jonsson, nor has the Examiner adequately explained why the claimed composition would have been obvious.

In particular, the Examiner finds that the Declaration sets forth "results of a study but do not provide in comparison form data showing how many experiments were conducted . . . , what result was achieved by administration of an active substance at a therapeutic dosage and what effect was achieved by the claimed combination" (Ans. 6). However, the Declaration states, for example, that the "combined administration of prednisolone and ultra low dose of prednisolone caused the reduction in the number of writhings by 30.6% ($p<0.05$) and in the pain sensitivity (% from the control) - by 26.4% ($p<0.05$) as compared to an isolated administration of prednisolone" (Dec. ¶ 7). The Examiner has not adequately explained why this recitation is inadequate. We therefore reverse the rejections over Jonsson of claim 23 and of claims 25-27, 33, 43, and 45[3]-48, which depend from claim 23.

With regard to the rejections over Cohen, Sirany, Nobile, Massey, and Bergel, the claims rejected over these references all depend from claim 23 and therefore require that the "combination possesses enhanced therapeutic properties in comparison with [the] active medicinal substance alone," as recited in claim 23. As with Jonsson, the Examiner has not adequately explained why Appellant's evidence fails to demonstrate that the claimed compositions are different from the compositions disclosed in Cohen, Sirany, Nobile, Massey, and Bergel, nor has the Examiner adequately explained why the claimed compositions would have been obvious. We

[3] We note that claim 45 actually depends from claim 35, which was cancelled (App. Br. 2). However, for the purpose of this appeal, we are assuming that claim 45 depends from claim 33.

therefore reverse the rejections over Cohen, Sirany, Nobile, Massey, and Bergel.

REVERSED

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